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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,542

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Unchalee Kositprapa

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/777,542	<b>Applicant(s)</b> KOSITPRAPA ET AL.	
	<b>Examiner</b> KEVIN WEDDINGTON	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 15, 17-20, 23-26 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 15, 17-20, 23-26 and 35-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

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Claims 1-4, 15, 17-20, 23-26 and 35-41 are presented for examination.

Applicants' amendment and response filed November 6, 2009 have been received and entered.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over Adjei et al. (6,403,121 B1) in view of Menon et al., The American Journal of Gastroenterology, Vol. 96, No. 5, pps. 1631-1634 (2001) as set forth in the previous Office action dated August 6, 2009 at page 3-6 is hereby withdrawn because the primary reference, Adjei et al., taught a core formulation comprising a first layer comprising pioglitazone which covers at least a portion of a core comprising the biguanide, metformin.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-4, 15, 17-20, 23-26 and 35-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-50 and 55-63 of copending Application No. 11/093,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because of record, for reason of record as set forth in the previous Office action dated August 6, 2009 at pages 2-3 as applied to claims 1-4, 15, 17-20 and 23-26 is hereby

**MAINTAINED.**

Claims 1-4, 15, 17-20, 23-26 and 35-41 are not allowed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 15, 17-20, 23-26 and 35-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/35940, hereby known as Lewis et al. in view of WO 99/47128, hereby known as Timmins et al.

Lewis et al. teach a pharmaceutical composition comprising a thiazolidinedione formulated upon the surface of a metformin hydrochloride core (see abstract). Lewis et al. teach the thiazolidinedione includes pioglitazone (see page 2, lines 35-40). Lewis et al. teach the surface layer including the thiazolidinedione comprises a disintegrant and wetting agent (see page 5, lines 5-10) where the disintegrant includes crospovidone or polyvinylpyrrolidone and sodium starch glycolate (page 5, lines 30-35) and the wetting agent includes sodium lauryl sulfate (page 5, lines 35-40), which is an ionic surfactant. Lewis et al. teach the composition can be formed into tablets, lozenges or capsules (page 4, lines 25-30).

The instant invention differs from the cited reference in that the cited reference does not teach the metformin hydrochloride core as a controlled release core.

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However, the secondary reference, Timmins et al., teaches a biphasic controlled release delivery system wherein the core contains the highly water soluble drug metformin HCL and has prolonged gastric residence (see the abstract) or controlled release (see page 2, lines 20-30). Timmins et al. teach osmotic tablets for highly water soluble drugs are well-known in the prior art (see page 13, lines 25-35). Timmins et al. teach metformin HCL administered in combination with another agent to produce results greater than possible from each of the medicaments alone (see page 20, lines 30-35) such as the thiazolidinedione, pioglitazone (see page 21, lines 30). Wherein the thiazolidinedione is incorporated as a separate rapidly dissolving layer (see page 22, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Lewis et al. in view of Timmins et al. Both Lewis et al. in view of Timmins et al. are drawn to a dosage form of a core of metformin coated with a thiazolidinedione such as pioglitazone. Generally, difference in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical, see MPEP 2144.05 IIA.

The instant invention differs from the cited references in that the cited references do not teach the pharmacokinetic profile of the dosage form. The limitations drawn to the pharmacokinetic profile of the dosage form are interpreted As functional limitation, reciting the purpose or intended use of the claimed product. Insofar as these limitation require a structural limitation of the instant invention as claimed, it is found that the

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Lewis et al. in view of Timmins et al. provide guidance for selecting these structural limitations absent a clear or convincing relationship between the limitations drawn to the pharmacokinetic profile of the dosage form as a required structure.

Claims 1-4, 15, 17-20, 23-26 and 35-41 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KEVIN WEDDINGTON whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm - 9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner  
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